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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,051	10/12/2001	Michael D. Mosk	88196/00-143	1803

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EXAMINER	
BOCKELMAN, MARK	
ART UNIT	**PAPER NUMBER**
3762	7

DATE MAILED: 12/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/977,051	MOSK ET AL.	
	Examiner	Art Unit	
	Mark W Bockelman	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *25 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-2, 8-12 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Johnson et al USPN 5,947,921. (Alone or in view of Alvarez "The healing of superficial skin wounds is stimulated by external electrical current" and Doan et al "In vitro effects of therapeutic ultrasound on cell proliferation, protein synthesis and cytokine production by human fibroblasts, and monocytes").

Johnson et al teaches the simultaneous (note column 24 lines 10-15) application of ultrasound in the range of less than 2.5 MHZ, in the 0- 1W/cm^2 and up to 1 mA/cm^2 current. Applicant has not set forth any particular parameter ranges in his specification in which dermal matrix protein generation is limited but merely describe preferred ranges. Notwithstanding, from the scope of claims 1 and 14, it would appear that any combination of ultrasound and electrical energy produce collagen generation. Johnson meets this criteria. Moreover, Johnson applies combinations of ultrasound and electrical energy in applicant's preferred ranges and thus the examiner concludes the Johnson drug delivery method would also inherently result in collagen production. It is noted that the discovery of a result that is not explicitly stated in a known method is not considered patentable over the known method.

Alternatively, to have realized that the combination of the Johson application would inherently result in collagen synthesis would have been obvious in view of the teachings of Doan et al and Alvarez that teach the synethisis of collagen within the Johnson et al parameter ranges.

4. Claims 1-2, 7-13 Johnson et al USPN 5,947,921. (Alone or in view of Alvarez "The healing of superficial skin wounds is stimulated by external electrical current" and Doan et al "In vitro effects of therapeutic ultrasound on cell proliferation, protein synthesis and cytokine production by human fibroblasts, and monocytes") are rejected under 35 U.S.C. 103(a) as being unpatentable over Henley

USPN 5,538,503 in view of Johnson et al USPN 5,947,921. Henley teaches the application off electical energy in the form of pulsed waves of 10-300Hz, 10-40 volts in combination with ultrasound but does not teach applicant's perferred power or ultrasonic frequency range. As noted in item 2 of this office action Johnson teaches standard frequency ranges and power levels for drug delivery that correspond to the preferred ranges taught by applicant. To have used these ranges would have been obvious since they are standard in the art for delivering drugs and would inherently generate collagen in accordance with applicant's diosclosure.

5. Claims 1- 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al in view of Johnson and further in view of Alvarez et al "The healing of superficial skin wounds is stimulated by external electrical current" and Doan et al "In vitro effects of therapeutic ultrasound on cell proliferation, protein synthesis and cytokine production by human fibroblasts, and monocytes"

While Zhang et al teaches the application of ascorbic acid to wounds in the background of the invention, and teaches that ultrasound may be administered simultaneously along with

iontophoresis and electroporation (column 9 lines 45-50) with electrical pulsing with in applicant's disclosed frequencies and field strengths (column 11 lines 5-17) he does not teach the application of his electroporation/ultrasound in applicant's preferred ultrasound range or a method of treating a preexisting wound. However, as noted above, to have used the ultrasonic frequecies and power setttings of johnson would have been conventional to achieve bettter drug delivery. In additonthe examiner considers it obvious to have applied the method to a wound that was created by injury since his method deals with healing the skin via collagen formation. Alternatively to have produced a wound in the skin to test the healing capabilies of the Zhang et al method would have been obvious in view of the teachings of Alvarez who induces keratome wounds in test animals for purposes of testing the collagen synthesis capabilities of his method. To have realized the further benefits of ultrasound in wound healing as taught by Doan et al would have been obvious.

Response to Arguments

6. Applicant's arguments with respect to claims 1-28 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Bockelman whose telephone number is (703) 308-2112. The examiner can normally be reached on Monday through Friday from 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes, can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3591.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

MWB

December 29, 2003

MARK BOCKELMAN
PRIMARY EXAMINER